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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,774	10/29/2001	Alessandra D'Azzo	2427/1F509-US1	9922
29311	7590	09/12/2005	EXAMINER	
DARBY & DARBY			FRONDA, CHRISTIAN L	
P.O. BOX 5257			ART UNIT	PAPER NUMBER
NEW YORK, NY 10150-5257			1652	

DATE MAILED: 09/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

## *JK*

### Office Action Summary

Office Action Summary	Application No.	Applicant(s)
	10/014,774	D'AZZO ET AL.
	Examiner Christian L. Fronda	Art Unit 1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 14 June 2005.
- 2a) This action is FINAL.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-10, 13-20 and 22-33 is/are pending in the application.
  - 4a) Of the above claim(s) 1-8, 18 and 21-33 is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 9, 10, 13, 15-17, 19 and 20 is/are rejected.
- 7) Claim(s) 14 is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on 29 October 2001 is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \* c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

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## **DETAILED ACTION**

1. Previously withdrawn claims 9, 10, and 13 have been included with the examined claims 14-17, 19, and 20 in view of applicants' amendment to the claims filed 06/14/2005, where the claims have been amended to the elected sequence of SEQ ID NO: 2.
2. Claims 9, 10, 13-17, 19, and 20 are under consideration in this Office Action.
3. The objection to claim 14 has been withdrawn in view of applicants' claim amendments filed 06/14/2005.
4. The rejection of claims 15-17, and 19 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement has been withdrawn in view of applicants' claim amendments filed 06/14/2005.
5. The rejection of claims 15-17 and 19 under 35 U.S.C. 103(a) as being unpatentable over Guan et al. in view of Prinos et al. has been withdrawn in view of applicants' claim amendments filed 06/14/2005.

### *Claim Rejections - 35 U.S.C. § 112, 1st Paragraph*

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:  
The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.
7. Claims 9, 10, 13, 15-17, 19, 20 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated nucleic acid encoding an Ozz protein wherein the Ozz protein is expressed only in cardiac and skeletal muscle and consists of the amino acid sequence of SEQ ID NO: 2; does not reasonably provide enablement for any and all types of isolated nucleic acid encoding an Ozz protein wherein the Ozz protein is expressed only in cardiac and skeletal muscle, comprises about 285 amino acids, and shares about 90%-92% sequence

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similarity with SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with this claim.

Factors to be considered in determining whether undue experimentation is required, are summarized In re Wands [858 F.2d 731, 8 USPQ 2nd 1400 (Fed. Cir. 1988)]. The Wands factors are: (a) the quantity of experimentation necessary, (b) the amount of direction or guidance presented, (c) the presence or absence of working example, (d) the nature of the invention, (e) the state of the prior art, (f) the relative skill of those in the art, (g) the predictability or unpredictability of the art, and (h) the breadth of the claim.

The nature and breadth of the claims encompass any isolated nucleic acid encoding an Ozz protein wherein the Ozz protein is expressed only in cardiac and skeletal muscle, comprises about 285 amino acids, and shares about 90%-92% sequence similarity with SEQ ID NO: 2. The specification discloses a an isolated nucleic acid of SEQ ID NO: 1 encoding an Ozz protein expressed only in cardiac and skeletal muscle and consists of the amino acid sequence of SEQ ID NO: 2.

However, the specification does not provide guidance, prediction, and working examples for making any and all types of isolated nucleic acid encoding an Ozz protein wherein the Ozz protein is expressed only in cardiac and skeletal muscle, comprises about 285 amino acids, and shares about 90%-92% sequence similarity with SEQ ID NO: 2.

Thus, an undue amount of trial and error experimentation must be preformed to search and screen for the specific nucleotides to change (e.g., nucleotide deletion, insertion, substitution, and combinations thereof) that will result an isolated nucleic acid encoding a functional Ozz protein that shares about 90%-92% sequence similarity with SEQ ID NO: 2. General teaching from the specification regarding screening and searching for the claimed invention is not guidance for making the claimed invention.

In view of the above considerations, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with the claims.

8. Claim 20 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants' arguments filed 06/14/2005 have been acknowledged but are not persuasive. Applicants' position is that one could sequence any nucleic acid that hybridizes to SEQ ID NO: 1

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and compare it to the sequence of PPCA exon Ia

The nature and breadth of claim 20 encompass any isolated nucleic acid consisting of at least 10 consecutive nucleotides of SEQ ID NO: 1 that hybridizes under the recited stringent conditions, with the proviso that the nucleic acid is not a PPCA exon Ia. As stated in the previous Office Action to meet the enablement requirement, one skilled in the art must be able to make and/or use the invention of claim 20 without undue experimentation using the specification coupled with information known in the art.

The specification does not provide guidance, prediction, and working examples regarding how to search and screen for the claimed 20 nucleic acid that does not hybridize to the PPCA exon Ia. Thus, one must perform an enormous amount of trial and error experimentation to determine the specific hybridization conditions that would exclude PPCA exon Ia from hybridizing to SEQ ID NO: 1. Such experimentation is undue and well outside of routine experimentation. Teaching regarding screening and searching for the claimed invention is not guidance for making the claimed invention.

In view of the above considerations, one skilled in the art cannot make the invention without undue experimentation and thus, is not enabled by the specification.

### ***Conclusion***

9. No claim is allowed.

10. Claim 14 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

11. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37

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CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christian L Fronda whose telephone number is (571)272-0929. The examiner can normally be reached Monday-Friday between 9:00AM - 5:00PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura N Achutamurthy can be reached on (571)272-0928. The fax phone number for the organization where this application or proceeding is assigned is (571)273-8300.

13. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLF



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